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Oliff & Berridge  
PO Box 19928  
Alexandria, VA 22320

EXAMINER

HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 08/27/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n N .

09/701,243

Examiner

Kenneth R Horlick

Applicant(s)

MOUGIN ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 13-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 (2 pages) 6) ☐ Other:

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1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The critical element in the claimed methods is the use of blocking sequences.

2. The specification is objected to because of the following informalities:

A) there is no heading "Brief Description of the Drawings";

B) "[sic]" appears on pages 2, 6, and 9.

Correction is required.

3. Claims 13-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) These claims are confusing because they are drawn to methods, but no clear, active step(s) are recited in independent claim 13. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion. See Ex parte Erlich, 3 USPQ2d, p. 1011 (Bd. Pat. App. Int. 1986). Language such as "the method using" and "consists in adding" do not satisfy this requirement.

B) Claims 14-24 are further confusing because of the language "characterized in that", as it cannot be determined how the claim scope is affected. It is suggested that typical U.S. claim language be substituted, such as "wherein".

C) Regarding claim 15, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

D) Claim 21 is confusing because of the language "in particular" and "preferably", as affect on the claim scope is unclear. Applicant may wish to consider the use of dependent claims to cover the intended limitations.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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5. Claims 13-20 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Rampersad et al. (US 5,830,712):

These claims are drawn to methods relating to the use of blocking sequences, wherein said sequences hybridize to regions in between amplification primers and block extension/amplification of undesirable variant nucleic acids which would otherwise be amplified along with a desired target sequence.

Rampersad et al. clearly disclose this same method; see abstract, and columns 2-4 and 6. The teachings include modified nucleotides, non-nucleotide blocking agents, and blockage at either the 5' or 3' end of the blocking sequence.

6. Claims 13, 14, 16, 17, and 19 are rejected under 35 U.S.C. 102(b) or (e) as being clearly anticipated by Yu et al. or the corresponding patent to Steinman (US 5,849,497), respectively. These references clearly teach the method being claimed; see pages 714-720 of Yu et al. and columns 3-10 and 13-14 of Steinman.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rampersad et al.

These claims are drawn to the methods as discussed and rejected above, further wherein the element of the blocking sequence responsible for preventing amplification involves: at least five nucleotides and/or modified nucleotides; sufficient length such that a loop is formed; a specific substitution at the 3' end; or a specific substitution at the 5' end.

While Rampersad et al. do not explicitly disclose these blocking means, they recite in column 3: "[a]ny modification to the terminal nucleotides of the blockers that would function to retard 3' extension and 5' degradation is appropriate to allow the blocker to effectively inactivate the undesirable nucleic acid. Examples of such modifications include addition of an amine, phosphate, acridine or cholesterol group to a terminal nucleotide. Terminal phosphorothioate nucleotide bases are also effective modifications". Thus, it is clear that Rampersad et al. are merely citing examples of useful blocking elements, and that the skilled artisan would have been well aware of other appropriate elements for accomplishing the same goal. It is readily apparent that the further limitations of these claims relate to blocking elements well known and

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commonly used in the art at the time of the invention, and as such do not bear on patentability. Nothing in the specification indicates that applicants believe they have invented a novel and unobvious means of providing a blocked primer. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

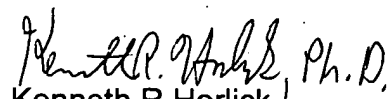
8. Adams (US 6,207,368 and US 6,180,338) are made of record as references of interest.

9. No claims are free of the prior art.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Kenneth R Horlick  
Primary Examiner  
Art Unit 1637

08/19/03